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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,765	01/23/2002	Eric Begleiter	70126-47961	8373
21874 7590 10/18/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
			EXAMINER TRAN, SUSAN T	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/031,765	Applicant(s) BEGLEITER, ERIC	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 9-72 is/are pending in the application.
- 4a) Of the above claim(s) 29-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 9-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/26/07 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7 and 9-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begleiter EP 0 217 821 B1 (Begleiter I), in view of Begleiter II (Edible Holography).

Begleiter I teaches an edible holographic element comprising a polymer such as hydroxypropyl methylcellulose (column 2, lines 13-30). The edible holographic further comprises plasticizer such as polyhydric alcohol and dextrose (column 2, lines 49 through column 3, lines 1-33).

Begleiter I does not teach the pharmaceutical dosage form comprising active substance. However, Begleiter II teaches a holographic composition for compressed candies, children's vitamins, and form of brand identification (page 104). Begleiter II further teaches a holographic composition comprising cellulose such as HPMC (page 103). Thus, it would have been obvious to one of ordinary skill in the art to modify the teachings of Begleiter I in view of the teachings of Begleiter II to obtain the claimed invention, because Begleiter I teaches an edible holographic composition suitable for candies and other food products, and because Begleiter II teaches holographic can be applied to food products such as candies, children's vitamins, and other form of brand ID.

Response to Arguments

Applicant's arguments filed 07/26/07 have been fully considered but they are not persuasive.

Applicant argues that Begleiter II teaches away from both the end-product decorated confections of Begleiter I as well as its manufacturing methods and materials. Begleiter II teaches no pharmaceutical with a thermoformable layer, as claimed, nor any special layer that carries a microrelief/diffraction grating.

However, In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined

teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present case, Begleiter II teaches a holographic composition for compressed candies, children's vitamins, and form of brand identification (page 104). Begleiter II further teaches a holographic composition comprising cellulose such as HPMC (page 103). Vitamins formulations are pharmaceutical dosage forms, and cellulose such as HPMC is thermoformable.

Applicant argues that the cited references themselves teach away from combining their teachings to make pharmaceuticals. It is improper to combine them, with hindsight, to say the present invention is "obvious." The Examiner also notes that the Begleiter II mentions HPMC. But, as she notes, so does Begleiter I. Neither reference teaches using HPMC to make a pharmaceutical. Begleiter I teaches a direct "cold" compression of a powder. There is no reason to disregard the clear teaching of part 4, page 104, of the Begleiter II article to somehow, for some unexplained reason, combine the teachings of these two references.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA

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1971). Both references teach the desirability of putting holographic image onto candy and other food products. Begliter II teaches candy includes kid vitamin candy. As discussed above, vitamins formulations are pharmaceutical dosage forms, and cellulose such as HPMC is thermoformable.

Applicant states that it is not certain what the Examiner has in mind by the phrase "side-by-side comparison," but as understood, this is exactly what the Declaration does – it compares the structure and operation, over time, of the products taught by Begleiter (EP'821) and Begleiter II with the present claimed invention. The Declaration is very clear that the prior art (including the only express reference to a pharmaceutical product with a holographic pattern, the Part 4 cold compressed powder product) were not "stable" as claimed here. The present claimed pharmaceutical dosage form with a stable holographic pattern is a dramatic, basic, and unexpected result. It took years of work, as detailed by the Applicant and author of both of the cited references, to discover the present claimed invention with a stable pattern, and that for the first time provided a commercially viable pharmaceutical dosage form. The factual evidence of record refutes the allegation of obviousness. As a matter of law, if the factual statements are not refuted, they must be taken as true. The pending claims are patentable and should be allowed.

However, the Declaration does not provide any example, data, or exhibit showing what is claimed to be "stable" versus the "unstable" holographic dosage of the prior arts. How can it be determined if the dosage form is unstable? How long after storage? And under which storage conditions?

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It was argued that applicant is not aware of any reasoned application by the Examiner of the cited prior art as teaching or suggesting the features defined by claims 3-5, and 19-24 with respect to a controllable stability that gives a visual indication of the environmental history of the product. These claims are clearly allowable.

However, the cited prior arts teach the claimed holographic dosage form using the claims material, namely, HPMC as a thermoformable material. The burden is shifted to applicant that the holographic dosage of the prior art does not exhibit the claimed properties.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SUSAN TRAN
PRIMARY EXAMINER

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